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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,204	03/22/2004	Lydie Bougueleret	54720-8015.US00	3710

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/807,204

Applicant(s)

BOUGUELERET ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/22/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I, claims 1-7, 16 and 17 in the response filed August 10, 2005 is acknowledged. Non-elected claims 8-11 and 24-28 have been cancelled, therefore, claims 1-7, 16 and 17 are examined.

### *Informalities*

The disclosure is objected to because of the following informalities:

2. The specification (e.g., page 18, line 8; page 43, line 1) cites embedded hyperlinks and/or other forms of browser-executable code, which are impermissible and require deletion.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-7, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-7, 16 and 17 are directed to a DJ11 polypeptide comprising a Kunitz-type protease inhibitor domain or a biological active portion thereof, wherein the polypeptide comprises an amino acid sequence having at least 98% sequence identity to the sequence of residues 77 to 127 of SEQ ID NO:1 or residues 52 to 102 of SEQ ID NO:2. The specification

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indicates that the DJ11 encompasses polypeptides having an amino acid sequence of SEQ ID NO: 1 and 2, including natural variants and fragments thereof, and DJ11 may also contain mutant polypeptides, such as deletion, addition, swap, or truncation mutants, and preferred DJ11 polypeptide retain at least one biological activity of the DJ11 of SEQ ID NO:1 or 2 (page 11; lines 15-35); and it further defines biological activities of DJ11 protein (page 12, lines 1-13). However, the specification has not identified various DJ11 polypeptides (i.e., amino acid sequences having at least 95% sequence identity to SEQ ID NO:1 or 2, fragments or mutants of SEQ ID NO:1 or 2) other than SEQ ID NO:1 or 2, nor has demonstrated these DJ11 polypeptides have DJ11 biological activity, and there are no working examples demonstrating the claimed DJ11 polypeptide variants, fragments or mutants having DJ11 biological activity. Furthermore, there is no description of any particular structure to function/activity relationship in the disclosed species. Without guidance on the correlation of structure to function/activity of DJ11 polypeptide variants or fragments, one skilled in the art would not know whether these peptide variants would have DJ11 biological activity. The lack of description of the correlation of structure to function/activity of peptide variants, and the lack of representative species for the DJ11 polypeptide variants, fragments and mutants as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-7, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 1-7, 16 and 17 are indefinite as to whether the amino acid sequence of residues 77 to 127 of SEQ ID NO:1 or residues 52 to 102 of SEQ ID NO:2 is a Kunitz-type protease inhibitor domain or a biological active portion thereof since the claim recites the DJ11 polypeptide comprises a Kunitz-type protease inhibitor domain or a biological active portion thereof, in the mean time, it also recites the polypeptide comprises an amino acid sequence having at least 98% sequence identity to the sequence of residues 77 to 127 of SEQ ID NO:1 or residues 52 to 102 of SEQ ID NO:2. Claims 2-7, 16 and 17 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

6. Claims 2, 3 and 17 recite the limitation "fragment thereof" in lines 1-2. There is insufficient antecedent basis for this limitation in claim 1.

7. Claim 6 is indefinite because of the use of the term "substantially purified". The term cited renders the claim indefinite, it is not clear to what extent the polypeptide is purified, e.g., is it 90% or 80% pure?

8. Claim 7 is indefinite because of the use of the term "wherein said polypeptide comprises at least one amino acid deletion, substitution or insertion". The term cited renders the claim indefinite, it is not clear what are the metes and bounds for the number/location of deletion, substitution or insertion in the sequence. Claim 7 is also indefinite as to claim 7 does not further limit the claim from which it depends from.

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9. Claim 16 is indefinite as to claim 16 does not further limit the claim from which it depends from, since the claim recites the DJ11 polypeptide comprising at least 12 contiguous amino acids of SEQ ID NO:1, wherein the polypeptide has at least one DJ11 biological activity, while the independent claim, claim 1, recites the DJ11 polypeptide comprises an amino acid sequence having at least 98% amino acid identity to the sequence of residues 77 to 127 of SEQ ID NO:1 or residues 52 to 102 of SEQ ID NO:1.

***Conclusion***

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner



**CHIH-MIN KAM  
PATENT EXAMINER**